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1-7-04

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re application : Lovell, et al.
Serial No. : 09/328,120
Filed : June 8, 1999
Appeal No. :
Title : NOSE MASK

Art Unit : 3761
Examiner : Dawson, G.
Docket No.: SLP-005

MS Appeal Brief - Patents
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

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APPELLANT'S BRIEF UNDER 37 CFR 1.192

The following brief is submitted in connection with an appeal taken in the above-identified application, subsequent to the Notice of Appeal filed on August 18, 2003. This brief is submitted in triplicate pursuant to 37 CFR 1.192(a) and is accompanied by the fee set forth in 37 CFR 1.17(c). A Petition for a one month extension of time under 37 CFR 1.136(a) is also filed herewith.

REAL PARTY IN INTEREST

The real party in interest is SleepNet Corporation, the assignee pursuant to an assignment recorded at reel 010205, frame 0965.

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STATUS OF CLAIMS

Claims 1-18 have been cancelled. Claims 19-29 are currently pending and have been rejected. The rejection of claims 19-29 is appealed. A copy of claims 19-29 is provided in the APPENDIX.

STATUS OF AMENDMENTS

No amendment has been filed subsequent to final rejection.

SUMMARY OF INVENTION

The present invention features a seal 2, 202 for use with a nasal mask 1, 201. The seal 2, 202 comprises a bladder (e.g., formed from film 60, 64) filled with a molded material 62 having a durometer value less than about ten on a Shore 000 scale. *See* Specification, page 14, lines 6-12, and page 16, lines 1-14. The seal 2, 202 is configured to seal against external skin proximate at least one naris at a base of a nose of a user. *See* Specification, page 7, lines 11-14; page 11, lines 18-22; page 13, lines 1-3; and page 19, lines 5-6.

In one embodiment, the bladder is substantially planar on one side for contacting a shell 6 of a nasal mask and has at least one protrusion (e.g., domes 38, 40) on another side for contacting the external skin. *See* Specification, page 17, lines 10-12. One embodiment of the seal 2 has a generally oval shape. *See* Specification, page 17, line 13. A further embodiment of the seal 2 has a concave area 78. *See* Specification, page 17, line 14.

ISSUE

Whether claims 19-29 are unpatentable under 35 U.S.C. §103 as obvious over U.S. Patent No. 3,725,953 to Johnson et al. (the “Johnson patent”).

ARGUMENT

In rejecting all of the claims in the present application, the examiner relies on a single prior art reference – the Johnson patent. The Johnson patent discloses a diver’s mask having a resilient seal 20 “designed to accommodate differing facial features by including a suitably shaped layer of pliable neoprene 21 wrapped about and bonded onto a length of resilient surgical

rubber tubing 22.” See Johnson patent, col. 2, lines 42-45. The examiner contends that the pliable neoprene 21 is the bladder recited in claim 19 and the rubber tubing 22 is the molded material recited in claim 19. See Office action, page 3. The examiner further contends that the claimed durometer value of “less than about ten on a Shore 000 scale” and the other claimed limitations defining the shape and thickness are all considered to be “obvious design choices.” Id.

Appellant submits that the examiner has not established a *prima facie* case of obviousness because the examiner has failed to establish that the prior art suggests the desirability of the proposed modification to the Johnson patent. Because the examiner was unable to produce a *prima facie* case of unpatentability, the applicant is entitled to grant of the patent. In re Oetiker, 977 F.2d 1443, 1445, 24 USPQ2d 1443, 1444 (Fed. Cir. 1992).

I. The Claimed Durometer Value Was Not an Obvious Design Choice

In rejecting claims 19-29 as obvious over the Johnson patent, the examiner erred by improperly relying on the obvious design choice rationale to support the modification of the Johnson patent. To establish a *prima facie* case of obviousness, there must be some suggestion or motivation, either in the references themselves or in the knowledge generally available to one of ordinary skill in the art, to modify the reference. See MPEP §2142 (8th Ed., Rev. 1). See also, In re Rouffet, 149 F.3d 1350, 1357, 47 USPQ2d 1453, 1457-58 (Fed. Cir. 1998). The only rationale given by the examiner for modifying the Johnson patent is as follows:

Lacking criticality, the examiner considers all of these features to be obvious design choices, noting that it would appear as though the prior art seal would perform equally as well as the applicant’s seal as the prior art seal is disclosed as being useful to seal against faces having differing contours. No advantage, particular purpose or solution to a problem was disclosed by the applicant. Therefore, it would have been an obvious matter of design choice to modify Johnson to obtain the invention as specified in claims.

Office action, page 3.

Because the Office action fails to mention any suggestion or motivation in the references or in the knowledge generally available to one of ordinary skill in the art, the examiner appears to be relying on legal precedent as the source for the rationale supporting this rejection. To rely on legal precedent, the facts of a prior legal decision must be sufficiently similar to those in an application under examination. See MPEP §2142. The examiner has failed to provide any

citation of supporting case law, much less establish that the facts of a prior case are sufficiently similar to those in the present case. For this reason, appellant submits that the examiner has failed to establish a *prima facie* case of obviousness.

Moreover, the modification required for the seal disclosed in the Johnson patent to meet the claimed durometer value is not the type of modification that should be deemed a mere “design choice.” This is not merely a matter of changing the size or shape of an element or optimizing a range. See MPEP §2144.04 (refers to examples of legal precedent involving obvious design choice). To meet the claimed durometer value, this modification of the Johnson patent requires a complete substitution of material. Although the Johnson patent fails to disclose a specific durometer value for the resilient surgical rubber tubing 22, the durometer value of this type of rubber material typically ranges from 27 to 53 on a Shore A scale, which is substantially higher than the range recited in claim 19. See, e.g., Dipped Hytone® Natural Rubber Latex Tubing Typical Properties, Hygenic Corporation http://www.hygienic.com/english/dipped_tubing_technical_specs.html (last accessed May 14, 2003); Natural Rubber Latex Tubing Products Specifications, Kent Elastomer Products, Inc. (1999); and Surgical Tubing Specifications, Reef Scuba Accessories http://reefscuba.com/surgical_tubing_specs.htm (last access on May 14, 2003) (Exhibit A). To modify the seal in the Johnson patent to have a material with the claimed “durometer value less than about ten on a Shore 000 scale,” would require the surgical tubing material 22 be replaced with a material capable of having such a low durometer value. This is not merely a matter of slightly changing or optimizing the durometer value of surgical rubber material. Thus, appellant submits that the examiner has failed to establish a *prima facie* case of obviousness the “obvious choice of design” rationale should not be applied to a modification that requires a substitution of materials having substantially different properties.

Even if the durometer value were merely a “design choice” as asserted by the examiner, the “design choice” would not have been obvious. In the cases related to obvious design choices, the court has generally held that the rationale of “obvious matter of design choice” applies when a modification is made which “solves no stated problem.” See In re Chu, 66 F.2d 292, 36 USPQ2d 1089 (Fed. Cir. 1995); In re Kuhle, 526 F.2d 553, 555, 188 USPQ 7, 9 (CCPA 1975).

In the present case, the problems solved by the “durometer value less than about ten on a Shore 000 scale” are clearly stated in the specification, as was previously explained in the Response dated May 19, 2003. The present specification refers to a need to overcome the limitations of known designs by providing an improved nasal mask that provides a consistent reliable nasal area seal, while being comfortable to wear. See present specification, page 3, lines 19-21. The seal should be comfortable and conform well to nasal area because these nasal masks are worn for extended periods (e.g., during sleep). See present specification, page 2, lines 1-6. One problem associated with nasal masks relates to the conformance of the mask to the nasal area, which is complexly contoured and differs from patient to patient. See present specification, page 2, lines 7-8. If the mask does not form a good seal around the patient’s nose, leakage can occur, reducing the effectiveness of the treatment. See present specification, page 2, lines 11-12. The softness of the material (i.e., the low durometer value) used in the seal according to the present invention contributes to the comfort and reliability (i.e., the ability to conform to the nasal area) of the seal. See present specification, page 4, lines 5-8, page 7, lines 11-21. Thus, appellant submits that the examiner has failed to establish a *prima facie* case of obviousness because the claimed durometer value solves a problem stated in the specification.

Because the examiner erred in concluding that the durometer value recited in independent claim 19 is an obvious choice of design, the examiner has failed to establish a *prima facie* case of obvious with respect to claim 19 and the claims dependent therefrom.

II. The Prior Art Teaches Away From the Claimed Durometer Value

In rejecting claims 19-29 as obvious over the Johnson patent, the examiner erred by ignoring disclosures that teach away from the proposed modification of the Johnson patent. The prior art must be considered in its entirety including disclosures that teach away from the claims. See MPEP §2141.02. The proposed modification cannot render the prior art unsatisfactory for its intended purpose. See In re Gordon, 733 F.2d 900, 221 USPQ 1125 (Fed. Cir. 1984). The proposed modification also cannot change the principle of operation of a reference. See In re Ratti, 270 F.2d 810, 123 USPQ 349 (CCPA 1959).

The diver’s mask disclosed by the Johnson patent is intended to be worn under water. To maintain an adequate seal and compensate for changes in pressure, the mask includes pressure

compensation holes 22a, which allow air to be passed into the interior of the tube 22. See Johnson patent, col. 3, lines 24-34. If these holes 22a were omitted, the tube 22 would collapse under increasing ambient pressure and the mask would lose its seal. See Johnson patent, col. 3, lines 34-37.

If the pliable neoprene 21 were filled with a material having a durometer value less than about ten on a Shore 000 scale, as proposed by the examiner, the material having this durometer value would be soft enough to squeeze at least partially through the holes 22a. As a result, air would be prevented from passing through the holes 22a to compensate for changes in pressure, rendering the diver's mask unsatisfactory for the intended purpose stated in the Johnson patent. Also, the seal could become damaged if the material having the low durometer value squeezes through the holes 22a. To remove the holes 22a and properly contain the material having the low durometer value would change the principle of operation of the Johnson patent.

Moreover, the resiliency of the seal disclosed in the Johnson patent relates to the large hole in the rubber surgical tubing 22. See Johnson patent, col. 2, lines 53-58. To fill the neoprene 21 with the material having the durometer value less than about ten on the Shore 000 scale would essentially eliminate this large hole and would change the principle of operation of the seal in the Johnson patent. For these reasons, appellant submits that the proposed modification of the Johnson patent would not have been obvious to one of ordinary skill in the art.

Moreover, the examiner must consider all of the teachings in the prior art in making the obviousness determination. In particular, the teachings in International Patent Application Publication No. WO 97/0909 (the "Barnett reference") suggest that it would not be desirable to have a seal with the claimed durometer value. In particular, the Barnett reference teaches that a properly designed facial seal must substantially but not identically mimic human fat tissue from a structural, particularly a resiliency perspective. See Barnett reference, page 10, lines 24-34. The facial seal must exhibit some measurable recoil memory whereby it is structurally self-sustaining. See Barnett reference, page 10, lines 34-37. To achieve these properties, the Barnett reference discloses a facial seal 18 having an annular member 27 formed from a gel substance exhibiting a durometer on the Shore 000 scale from about 20 to about 45, whereas human fat

tissue registers a durometer of about 10 on the Shore 000 scale. See Barnett reference, page 11, lines 6-16.

Thus, the Barnett reference teaches one skilled in the art not to use soft material having a durometer value of less than about twenty on the Shore 000 scale in order to maintain some resiliency and structural integrity of the seal. This teaches away from a proposed modification that would replace the surgical rubber tubing in the Johnson patent with a material having a durometer value less than about ten on the Shore 000 scale.

Because the examiner erred by failing to consider the disclosures in Johnson patent and the Barnett reference, which teach away from the modification proposed by the examiner, the examiner has failed to establish a *prima facie* case of obviousness with respect to claim 19 and the claims dependent therefrom.

Conclusion

In summary, the examiner has erred by improperly relying on the "obvious design choice" rationale and by failing to consider prior art disclosures that teach away from the proposed modification of the Johnson patent. Accordingly, appellant submits that the examiner has failed to establish *prima facie* obviousness with respect to claims 19-29 and submits further that claims 19-29 would not have been obvious over the Johnson patent.

Respectfully submitted,

Date: 11-20-03

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APPENDIX

Claims:

19. A seal for use with a nasal mask, the seal comprising a bladder filled with a molded material in a predetermined configuration, the material having a durometer value less than about ten on a Shore 000 scale, wherein the seal is configured to seal against external skin proximate at least one naris at a base of a nose of a user.
20. The seal of claim 19 wherein the bladder is substantially planar on a side thereof for contacting a shell of the nasal mask.
21. The seal of claim 19 wherein the bladder has at least one protrusion on a side thereof for contacting the external skin proximate at least one naris at a base of a nose of a user.
22. The seal of claim 19 wherein the seal has a thickness and forms at least one aperture therethrough disposable proximate a naris.
23. The seal of claim 22 wherein a thickness of the seal proximate the aperture is less than a thickness of the seal remote therefrom.
24. The seal of claim 19 wherein the material comprises silicone.
25. The seal of claim 19 wherein the seal is about 0.225 inches thick.
26. The seal of claim 19 wherein the seal comprises a generally oval shape.
27. The seal of claim 19 wherein the seal comprises a concave area.
28. The seal of claim 19 wherein the seal comprises a convex arc.
29. The seal of claim 19 wherein the seal comprises a variable thickness.